

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3000779542	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-MAY-2017 DISTRICT: Dallas PRINTED BY FDA:21-JUN-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS			
	Establishment Functions														
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute						
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Bone Bank Allografts  4808 Research Drive San Antonio, Texas 78240  a. PHONE 210-696-7616 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X				X	X	X	X				*** See full text on next page	
	b. Cartilage		X				X	X	X	X				SteriGraft	
	c. Cornea														
	d. Dura Mater														
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	f. Fascia			X				X	X	X	X				SteriGraft
	g. Heart Valve														
	h. Ligament			X				X	X	X	X				SteriGraft
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	j. Pericardium			X				X	X	X	X				SteriGraft
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	l. Sclera														
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	n. Skin			X			X	X	X	X				SteriMatrix, FlowerDerm	
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Bone Bank Allografts Attn: Christy L. Martinelli 4808 Research Drive San Antonio, Texas 78240  a. PHONE 800-397-0088 EXT _____ b. PHONE _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	p. Tendon			X			X	X	X	X				SteriGraft	
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
<b>7. ENTER CORRECTIONS TO ITEM 6</b>	r. Vascular Graft														
	s. Amniotic Membrane			X			X	X	X	X				*** See full text on next page	
<b>8. U.S. AGENT</b>  a. E-MAIL _____	t. Amniotic Fluid			X			X	X	X	X				*** See full text on next page	
	u.														
	v.														
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Christy L. Martinelli b. E-MAIL cmartinelli@bonebank.com c. TITLE Director of Quality Assurance d. DATE 15-MAY-2017															

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PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION  
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,  
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**  
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2

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

- a. Bone           SteriGraft, SteriSorb, SteriFlex, SteriFuse, SteriScaf  
                      HSA
- Amniotic         SteriShield, SteriShield II, FlowerPatch,  
Membrane       FlowerAmnioPatch
- Amniotic Fluid   Amnios, SteriFlo, Amnios RT, FlowerFlo,  
                      FlowerAmnioFlo